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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,378	06/27/2000	Nick W. Warne	GI-5238BA	5593

30623 7590 07/30/2003

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
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ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/604,378

Applicant(s)

WARNE ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4 and 11-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 11-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. This office action is in response to the amendment and response filed on 4/09/03 in Paper No: 17. Claims 1, 3, 4 and 11-35 are pending. Claims 2, 5-10 and 36-46 have been cancelled.
2. Applicants have amended the priority information and updated the status of Application No: 09/179,026.
3. The change of title is acknowledged.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

**Claim Rejections - 35 USC § 112, first paragraph rejections are withdrawn**

5. Applicants amendments to claim 1, has obviated the previous rejection under 35 U.S.C. 112, first paragraph.

**Claim Rejections - 35 USC § 102(b), rejections are withdrawn**

6. Applicants arguments with respect to Bennnett et al. (U.S. Patent No. 5,215,895) has obviated the previous rejection of claims 1, 11-16, 18-19, 21-27, 29-30 and 34 under 35 U.S.C. 102 (b).
7. Applicants arguments with respect to Keith et al. (1994) has obviated the previous rejection of claims 1-4 and 11-35 under 35 U.S.C. 102 (b).

**Claim Rejections - 35 USC § 103(a) rejections are withdrawn**

8. Applicants arguments and amendments have obviated the rejection of claims 1-4 and 11-35 under 35 U.S.C. 103 (a) as being unpatentable over Keith et al. (1994) in view of Kaneko et al. (U.S. Patent No. 4,808,613).

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9. Applicants arguments and amendments have obviated the rejection of claims 1-4 and 11-35 under 35 U.S.C. 103 (a) as being unpatentable over Keith et al. (1994) and Kaneko et al. (U.S. Patent No. 4,808,613) in view of Dandiker et al. (U.S. Patent No. 5,425,950).

***New 35 USC § 112, first paragraph rejections***

10. Claims 1, 3, 4 and 11-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating oral mucositis with IL-11 in a topical formulation, does not reasonably provide enablement for a method for treating all mucositis with IL-11 in topical formulations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses the effect of topical IL-11 on treatment of oral mucositis (see pages 20-24 and 25-26, Examples 2 and 4). However, the claims recite, "treating mucositis" which encompasses both oral and gastrointestinal mucositis. The instant specification is non-enabling for a method of treating gastrointestinal mucositis in the absence of support to accomplish such treatment by the administration of a topical formulation comprising IL-11. IL-11 could not be administered with a predictable prognosis using the specification as guidance because the specification provides no examples nor is an enabling mechanism disclosed using IL-11 commensurate with the scope of the claims. Specifically, it is unclear how the administration of a topical formulation (even containing proteinase inhibitors) will be able to treat gastrointestinal mucositis. There is no guidance provided in choosing the topical formulation required for

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the treatment of a patient with gastrointestinal mucositis and how to administer this topical formulation. Applicants have also not provided any working examples to treat gastrointestinal mucositis. Thus, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claims 1, 3, 4 and 11-35 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention to treat gastrointestinal mucositis using a topical formulation containing IL-11.

11. Claims that are directed to the treatment of oral mucositis will be allowable over prior art.

#### **Contact Information.**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS  
July 27, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600